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Inspiratory Muscle Trainer Effectiveness in Chronic Obstructive Pulmonary Disease Rehabilitation Program

Nury Nudwinuringtyas,¹ Balqis Islamadina,¹ Cleopas Martin Rumende,² Telly Kamelia²

¹Division of Cardiorespiratory Rehabilitation, Department of Medical Rehabilitation, Faculty of Medicine Universitas Indonesia—Dr. Cipto Mangunkusumo Hospital Jakarta, Indonesia, ²Division of Respiriology and Critical Illness, Department of Internal Medicine Faculty of Medicine, Universitas Indonesia Dr. Cipto Mangunkusumo Hospital Jakarta, Indonesia

Abstract

Chronic obstructive pulmonary disease (COPD) is marked by persistent respiratory disturbance which results in altered health status as well as functional capacity. Pulmonary rehabilitation (PR) is a part of comprehensive therapy in patients suffering from respiratory disturbance. This study focused on inspiratory muscles exercise using the *inspiratory muscle trainer* (IMT), which is a form of a weight training exercise. This experiment was conducted at the COPD outpatient clinic of Dr. Cipto Mangunkusumo Hospital during the period of September 2017 until April 2018. Patients were recruited consecutively. The criteria for inclusion were stable COPD patient with GOLD criteria A-D and never received prior exercise for pulmonary rehabilitation. Patients underwent interview about their medical history followed by spirometry testing using Carefusion® and inspiratory muscle strength assessment using Micro RPM Carefusion®. The *St George Respiratory Questionnaire* (SGRQ) was used to assess the health status and the 6-minute walking test (6MWT) was conducted to assess the functional capacity. Subject exercised using IMT (Philips Respironic®) for eight weeks. Data were analyzed using paired t-test in statistical package for social sciences (SPSS) version 21. A total of 15 subjects with average age of 65.6±8.40 years old were recruited. Pre-post difference in inspiratory muscle strength was 11.31 cmH₂O, showing a statistically significant impact. The significant impact was also shown clinically through the results of the Minimal clinical important difference (MCID) on health status and functional capacity. The health status was evaluated using SGRQ with p exceeding 4%. A combined Pulmonary Rehabilitation (PR) and inspiratory muscles exercise program is proven to improve the health status and functional capacity.

Key words: COPD, *inspiratory muscle trainer*, pulmonary rehabilitation, SGRQ, 6MWT

Keefektifan *Inspiratory Muscle Trainer* pada Program Rehabilitasi Penyakit Paru Obstruktif Kronik

Abstrak

Penyakit paru obstruktif kronik (PPOK) ditandai dengan gangguan pernapasan yang persisten yang mengganggu status kesehatan dan kapasitas fungsional. *Pulmonary rehabilitation* (PR) merupakan bagian dari terapi komprehensif pasien dengan gangguan respirasi. Penelitian ini memfokuskan pada latihan otot inspirasi menggunakan *inspiratory muscle trainer* (IMT), suatu bentuk latihan otot pernapasan dengan pemberian beban. Eksperimen ini dilakukan di Rumah Sakit Cipto Mangunkusumo selama periode September 2017 hingga April 2018. Pasien direkrut secara *consecutive sampling*. Kriteria inklusi adalah pasien PPOK yang stabil dengan kriteria GOLD A-D yang belum pernah menerima latihan sebelumnya untuk rehabilitasi paru. Pasien menjalani wawancara, diuji dengan spirometri Carefusion®, dan kekuatan otot inspirasi dinilai menggunakan Micro RPM Carefusion®. St George Respiratory Questionnaire (SGRQ) digunakan untuk menilai status kesehatan dan *6-minute Walking Test* (6MWT) dilakukan untuk menilai kapasitas fungsional. Subjek menggunakan alat IMT (Philips Respironic®) selama 8 minggu. Data dianalisis menggunakan SPSS versi 21 dengan uji T berpasangan. Subjek penelitian berjumlah 15 orang dengan rerata usia 65,6±8,40 tahun. Kekuatan otot inspirasi awal didapatkan perubahan sebesar 11,31 cmH₂O, yang memberikan dampak bermakna dilihat dengan pencapaian *minimal clinical important difference* (MCID) pada status kesehatan dan kapasitas fungsional. PR bersama dengan program latihan otot inspirasi terbukti memberikan hasil perbaikan status kesehatan dan kapasitas fungsional.

Kata kunci: COPD, *inspiratory muscle trainer*, pulmonary rehabilitation, SGRQ, 6MWT

Corresponding Author: Nury Nudwinuringtyas, Department of Medical Rehabilitation, Faculty of Medicine, Universitas Indonesia—Dr. Cipto Mangunkusumo Hospital Jakarta, Jl. Diponegoro No.71, Jakarta Pusat, DKI Jakarta 10430 Indonesia, Email: nury_nus@yahoo.com

Introduction

Chronic obstructive pulmonary disease (COPD) is marked by persistent respiratory disturbance which alters one's health status and functional capacity.^{1,2} It is often associated with high economic burden and rarely stands as a single entity. Patients who suffers from COPD usually have one or two comorbidities, such as cardiovascular disease (34.8%), diabetes mellitus (22.8%), asthma (14.7%), and anemia (14.2%). In Europe, the estimated cost for respiratory disease reaches 6% of total health costs with 56% of it is the cost incurred due to COPD. In United States, COPD takes up to USD 29.5 billions, with an indirect cost of USD 20.4 billions. The highest average economic burden in one year period is seen in COPD patients with chronic liver disease as a comorbidity, which takes up USD 41,288, followed by COPD patients with anemia, which takes up USD 38,870.³

Pulmonary rehabilitation (PR) is an integrated part in comprehensive therapy for most patients with respiratory disturbance. It consists of training, education, and support which helps patients to breathe with maximum function. Moreover, it improves health status and quality of life.^{4,5}

Respiratory exercise is a main component of PR. This exercise can take the form of aerobic exercises, such as biking and walking which involve lower and extremity muscles. Exercise with ambulatory muscles is highly recommended (1A). In addition, exercises to decrease dyspnea are also included in category 1A.⁴ Respiratory muscle training, specifically inspiratory muscles, in the form of breathing exercise is intended to decrease dyspnea.⁴

This study focused on inspiratory muscle exercises, which was predicted to decrease symptoms in COPD and have impact on health status and functional capacity. The inspiratory muscle exercise used was the inspiratory muscle trainer (IMT), which is a form of respiratory muscle exercise using weight.

In 1997, the American College of Chest Physicians (ACCP) issued a recommendation to include IMT as a part of pulmonary rehabilitation program. The organization also stated, based on studies, that providing additional weight to inspiratory muscle during exercise is sufficient to increase inspiratory muscle strength, hence decreasing the incidence of dyspnea and preventing further decrease of functional capacity.⁶

Interventions in the current study was

given using Philips Respironic Inspiratory Muscle Trainer®. Impacts on inspiratory muscle strength, health status, and functional capacity were observed. Muscle strength was evaluated using Micro RPM Carefusion®. Health status was evaluated using St. George's Respiratory Questionnaire (SGRQ),⁷ while functional capacity is evaluated by 6-minute walk test (6MWT).^{2,7-9}

Methods

Pre- and post-test data collection of this study were conducted at the COPD outpatient clinic of Dr. Cipto Mangunkusumo General Hospital during the period of September 2017 to April 2018. Consecutive sampling was used to get sample for this study and ethical approval was granted by the Institutional Review Board (IRB) of the Faculty of Medicine, Universitas Indonesia (Ethical Clearance No. 355/UN2.FI/ETIK/2016). Inclusion criteria were stable COPD patient with GOLD criteria A-D, had never received pulmonary rehabilitation, and willing to participate in the study as evident by signing the written informed consent. The exclusion criteria were problems in the extremities and cardiovascular disease. Patients underwent interview to get their medical history, underwent spirometry testing by Carefusion®, and the inspiratory muscle strength was assessed using Micro RPM Carefusion®. The SGRQ was used to assess the health status and the 6MWT was conducted to assess the functional capacity.

The representative number of subjects required were calculated using a formula for experimental study, i.e. where t is the number of treated groups and n is the number of replications. When $t=1$ was used, the required number of subjects for this study was 16 patients. To anticipate the loss of unit experiment, correction was applied using $1/(1-f)$ formula where f is the unit proportion lost or withdrawn of 10%, resulting in $16+1.67=17.67$, giving 18 patients as the required number of subjects.

Subjects performed exercise using inspiratory muscle trainer (Philips Respironic®) for 8 weeks. Data for inspiratory muscle strength (*maximal inspiratory pressure*, MIP) and 6MWT were collected at the beginning of the intervention as baseline and during the second, fourth, sixth, and eighth week. Questionnaire (SGRQ) was completed at the beginning and end of study.

Training dose for IMT exercise was determined by the inspiratory muscle strength result and was adjusted in every evaluation.

Subjects were expected to do exercise twice a day for 15 minutes in each session with 30–70% intensity from the determined MIP score. Exercise was monitored and noted in a logbook.

Data were analyzed using the statistical package for social sciences (SPSS). Analysis of paired t-test was performed to see changes in the inspiratory muscle strength, functional capacity, and quality of life. Data obtained were then statistically analyzed with a p value of < 0.05.

Results

Table 2 lists the changes in inspiratory muscle strength. Evaluation was performed in every

Table 1 Research Subject Characteristic

Characteristic	n=15
Gender. n (%)	
Male	14
Female	1
Age (years. mean±SD)	65.6±8.40
GOLD. n (%)	
A	0
B	5
C	1
D	9
Initial MIP (cmH ₂ O. mean ± SD)	56.50±19.59
SGRQ (%. mean ± SD)	
Symptoms	47.45±19.07
Activity	58.59±24.40
Impact	34.07±15.39
Total	43.73±16.45
6-Minute Walking Test (Meter. mean ± SD)	340.36±87.72

Table 3 SGRQ Result (n=15)

SGRQ	Initial	Week 8	Δ SGRQ	P value
Symptoms n (%)	47.45±19.07	45.43±25.44	2.02	0.544
Activity n (%)	58.59±24.40	38.85±26.40	19.74	<0.001
Impact n (%)	34.07±15.39	21.21±15.62	12.86	<0.001
Total n (%)	43.73±16.45	30.58±18.55	13.15	<0.001

*paired t-test

Table 2 MIP Result (n=15)

	MIP (CmH ₂ O)	P value
Initial	56.50 ± 19,59	
Week 2	58.78 ± 19,76	0.452
Week 4	66.16 ± 20,56*	0.032
Week 6	65.59 ± 21,84	0.080
Week 8	67.81 ± 18,86*	0.021

*paired t-test

visit and the result was compared to the baseline score. A significant difference was found between the baseline (56.50±19.59 cmH₂O) and in week 4 (66.16±20.56 cmH₂O) and week 8 (67.81±18.86 cmH₂O).

SGRQ was evaluated twice (baseline and end of week 8). There was no significant difference in symptom. For activity and impact, as well as for the total score, significant differences were found. The total score difference was 13.15%, representing 13.15 units.

Six minute walking test was evaluated in inspiratory muscle strength through comparison with the baseline data. There were improved distance and the achievement of 6MWT. A significant improvement occurred after 4 (370.92 ± 103.83 meters) and 8 (391.90 ± 119.59 meters) weeks of IMT exercise compared to the initial distance (340.36 ± 87.72 meters).

Discussion

The number of subjects were calculated using an experimental study formula, resulting in 18 number of subjects (10% additional subjects to anticipate drop out). Subjects were referral patients from Department of Internal Medicine, Dr. Cipto Mangunkusumo General Hospital and were diagnosed as suffering from COPD. Twenty five patients were included with 15 of them finished the evaluation successfully. The number of male subjects was 14 and the average age of

Table 4 6-Minute Walking Distance Result (n=15)

	6-MWT Distance (meter)	P Value
Initial	340.36±87.72	
Week 2	360.38±97.84	0.161
Week 4	370.92±103.83*	0.017
Week 6	370.28±111.75	0.104
Week 8	391.90±119.59*	0.007

*paired t-test

subjects was 65.6±8.40 years old. The incidence of COPD increases in patients whose age was more than 40 years old.^{1,10-12}

Subject criteria included COPD GOLD A-D. Most subjects, 9 of 15 patients, were in GOLD D criteria. Assessment using GOLD was complex, especially because it is combined with symptom assessment to evaluate the mMRC and CA subjects with history of exacerbation. The GOLD D group means that subjects have CAT ≥10 and mMRC ≥2, with history of exacerbation ≥2, and fall into vulnerable group.¹

Table 1 presents the baseline data, SGRQ link to health status, 6MWT results link to functional capacity, and MIP that becomes the core of the study as the basis to determine exercise dose.

Maximal inspiratory pressure (MIP) and maximal expiratory pressure (MEP) are global measurements for respiratory muscle strength and implied inspiration and expiration pressure through a closed airway. The MIP gives a measurement of inspiratory muscle strength in sub-atmospheric pressure, while MEP provides a measurement of inspiratory muscle strength in supra-atmospheric pressure as a result of an activity by abdominal and intercostal muscles. Only inspiratory muscles strength is discussed here.

A study by Obando et al.,¹³ suggested a normal MIP for females over 40 years old as 59.3±18.8 cmH₂O and 86.8±27 cmH₂O for males over 40 years old. The average score is suggested to be 75±27 cmH₂O. initial MIP in this study is 56.50±19.59 cmH₂O. At the end of the study, the MIP is at 67,81±18.86 cmH₂O. A significant difference was observed during the baseline and end of week 8 (p<0.05). Inspiratory muscle strength improvement in this study was evaluated through changes in health status subjectively by patients and objectively using SGRQ and 6MWT. SGRQ is a questionnaire designed to measure health impairment in asthmatic and COPD

patients. It consists of three parts. The first part is about symptoms, followed by activity and impact. All three parts are combined and resulted in total score. In the first part, there are eight questions concerning symptoms based on what is felt by subjects to evaluate perception in breathing problems in terms of the frequency and severity. Symptoms include cough, sputum, and dyspnea. Data are obtained for the last three months up to one year. The second part of this questionnaire is about activities which measures disruption in daily activity. The third part is about impact which relates to psychosocial impairment.

The principles of SGRQ is scoring of each component. Every item in this questionnaire has its own score. The lowest is zero and the highest is 100. Scoring is done by dividing the total score by maximum score for that component and the result is translated into percentage. The total score is added to each component's score and the result is in percentage to its maximum score.¹⁴

SGRQ is done twice, at the beginning and the end of the study. In the present study, symptoms did not present any significant difference. This is in line with COPD definition from GOLD that stated COPD as a respiratory disturbance marked with persistent respiratory symptoms, although it is preventable and treatable.¹ This may correlate with the fact that most subjects of this study were GOLD D patients. The D group, as mentioned previously, has dyspnea assessment score of mMRC ≥ 2 which is the cutoff point that differentiate "less breathlessness" with "more breathlessness".

The terminology of Minimally Clinically Important Difference (MCID) was first used by Jaeschke et al., in 1989 with an argumentation that even though there are statistically different results, few cases show meaningless clinical impact. Jaeschke defined MCID as the least change in the lowest score which is felt as an improvement by patient.¹⁵

The MCID concept is a well known concept. In a study by Jones et al.¹⁶ on medicines used in COPD, the MCID for SGRQ is 4%. Another study suggested 13.15%. PR produces alteration in health status more significantly when compared to medications only.

In the present study, the different in 6MWT distance in baseline and at the end of week 8 is 51.54 meters. In a study by Jones et al.¹⁶ the MCID for medication only and for COPD patients, the results is 26±2 meters. This present study only includes IMT intervention and the distance is further compared to Jones' MCID.

Elmorisi et al.¹⁷ also evaluated the effect of IMT in 60 COPD patients who are divided into three groups, each consists of 20 subjects. All subjects still consumed medications at the time of the study. The first group performed peripheral muscle exercise with 30–60% intensity of IMT. The second group only performed peripheral muscle exercise, while the third group did not do any exercise. A decrease in total SGRQ of 32.67 unit and 27.7 unit is seen in the first and second group, respectively, while in the third group, i.e. without exercise, an increase of 4.49 unit was seen in SGRQ. Functional capacity as reflected by the distance of 6MWD was the highest in the first group, i.e. 90.55 meters. In group with ambulatory muscle training, the distance was 60.5 meters, and in group without exercise, the addition was minimal. i.e. 11.45 meters. The difference in the distance in the first two groups were statistically significant, but that is not the case for the third group.¹⁷ Clinically, a SGRQ difference of more than 4 units and distance more than 26±2 meters are also clinically significant.^{7,14,1}

McKenzie did *randomized controlled trial* on COPD patients. The intervention group received IMT, while the control group received sham IMT. IMT was given as a complement of PR after general exercise reconditioning. Magadle concluded a significant difference in inspiratory muscle strength change. Moreover, a significant decrease was found in total SGRQ of 60.1 to 56.3. In the first phase, the difference was 3.8 and in the second phase there was a continuous decrease ($p < 0.05$).¹⁸ Referring to Paul W. Jones and Mullevora, this increase correlates with clinical results.^{7,16}

Jones et al.¹⁶ found an increase in distance as much as 26±2 meters after intervention with medications. According to Jones, this also has clinical impact. McKenzie reported a significant difference in 6MWT between control and intervention groups. The intervention group that received IMT had an initial distance of 254 meters which increased to 322 meters (68 meters difference).¹⁸ This present study reported an increase of up to 50.54 meters in week 8.

Geddes et al.¹⁹ conducted a systematic review on COPD adult patients for inspiratory muscle exercise. Review criteria included subject aged over 18 years old, stable diagnosis of COPD with IMT or sham IMT intervention as well as without intervention. Geddes reviewed 19 articles which met the criteria out of 274 articles. Ten studies compared IMT with targeted dosage with sham IMT, two studies observed IMTs without

interventions, one study compared IMT in low versus high intensity, and six studies compared IMT without intensity target with sham IMT. Sixteen meta-analyses were reported. Evaluation was performed on inspiratory muscle strength, quality of life without using SGRQ, and functional capacity, which was evaluated by 6MWT. Increase in inspiratory muscle strength and 6MWT parameters were found.

The limitation of the present study lies in COPD grouping using GOLD and the minimum number of recruited subjects. The absence of a control group is another limitation. However, to counteract this situation, pre-intervention condition was considered as the control group in this study. Further research needs to be done in the future with more groups of subjects.

Pulmonary rehabilitation with exercise program is proven to produce results that are perceived by patients as improvement in health status and functional capacity. This is shown by increased distance in 6MWT that is clinically and statistically significant. This study was determined from the very beginning to give inspiratory muscle trainer (IMT). McKenzie and Geddes researches gave IMT as an adjunctive after muscle exercise for mobilization. Inspiratory Muscle Trainer alone improve health status and functional capacity. In GOLD D criteria patients, IMT can be safely given to COPD patients with the tendency of exacerbation with precaution dosage.

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